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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,641	09/25/2003	Thomas E. Wagner	035879-0165	4465
22428	7590	08/24/2006	EXAMINER	
FOLEY AND LARDNER LLP			QIAN, CELINE X	
SUITE 500				
3000 K STREET NW			ART UNIT	
WASHINGTON, DC 20007			PAPER NUMBER	
			1636	

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/669,641	Applicant(s) WAGNER ET AL.	
	Examiner Celine X. Qian Ph.D.	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
 4a) Of the above claim(s) 1-9 and 21-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 10-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>104,804,506</u> . | 6) <input type="checkbox"/> Other: ____. |

Art Unit: 1636

DETAILED ACTION

Claims 1-51 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group II in the reply filed on 7/27/06 is acknowledged. The traversal is on the ground(s) that all claims are sufficiently related and a search of all claims together would not place an undue burden to the office. This is not found persuasive because the invention of groups I-VII are patentably distinct for reasons set forth of the record mailed on 6/28/06. Although some of the claims may be related, they are distinct products or processes that are mutually exclusive and not obvious variants of each other. As such, a search of all groups in a single application is not co-extensive, and would have been burdensome.

The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 1-19, 21-51 are withdrawn from consideration for being directed to non-elected subject matter. Claims 10-20 are currently under examination.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 18 and 19 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 18 and 19 are rejected under 35 USC §101 because the claimed invention is directed to non-statutory subject matter. The term "cell" as defined by the specification at page

Art Unit: 1636

12 paragraph [041] states that the cell is present or intended to be present in a human being, and therefore being an inseparable part of the human itself. The scope of the claim, therefore, encompasses a human being, which is non-statutory subject matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-12 and 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Xiao et al (Journal of Virology, 1997. Vol 71, No. 2, pages 941-948, see IDS).

Xiao et al. disclose a plasmid that comprises four constructs that comprises 5'-3' (i) a first arm polynucleotide sequence; (ii) a spacer sequence, and (iii) a second arm polynucleotide sequence, wherein said second arm sequence is the complement of the first arm polynucleotide sequence and in the opposite orientation that forms hairpin loop (page 942, Figure 1&2 and legend). Xiao et al. also disclose said construct is flanked by EcoR I restriction sites which may be used to separate said construct with other constructs in the plasmid (see Figure 2e). Xiao et al. further disclose that E.coli SURE strain is transformed with said plasmid (see page 143, 2nd col., 2nd paragraph). Therefore, Xiao et al. disclose the instantly claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

Art Unit: 1636

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xiao et al.

The teaching of Xiao et al. are discussed above. However, Xiao et al. do not disclose a plasmid comprising at least 4, 6, 10 or 12 of said constructs.

It would have been obvious to one of ordinary skill in the art to make a plasmid comprising 4, 6, 10 or 12 of said constructs based on the knowledge known in the art as taught by Xiao et al. Xiao et al. already teach a plasmid that comprises two of said construct with detailed sequence information and use of said plasmid in rAAV vector production and plasmid delivery. Adding more construct that comprises the same sequence up to 12 copies is routine experimentation. The level of skill in the art is high. Absent evidence from the contrary, one of ordinary skill in the art would have reasonable expectation of success to make a plasmid comprises the claimed construct structure up to 12 copies. Therefore, the claimed invention is *prima facie* obvious at the time the invention was made.

Art Unit: 1636

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CELINE QIAN, PH.D.
PRIMARY EXAMINER

Celine X Qian Ph.D.
Examiner
Art Unit 1636

